

Application/Control Number: 09/509,377
Enclosure / to Applicant's reply of Sept. 1, 2004

Page 25

Reply under 37 CFR 1.116 -
EXPEDITED PROCEDURE -
Technology Center 3739

Enclosure No. 5

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,377	08/28/2000	Sergey Matasov		9553

United States Patent and Trademark Office
Commissioner for Patents
Art Unit 3739
Examiner Mr. Leubecker, John P.
P.O. Box 1450, Alexandria VA 22313-1450
United States of America

EXAMINER	
LEUBECKER, JOHN P	
ART UNIT	PAPER NUMBER

3739

DATE MAILED: September 3, 2003

RECEIVED
CENTRAL FAX CENTER

SEP 02 2004

REMARKS / ARGUMENTS

Claims 1-20 have been amended.

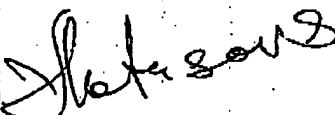
Examiner has acknowledged that claims 1-20 have now been amended to clear up all Examiners' objections.

Attached hereto is a marked-up version of the changes made to the specification, claims and drawings by the current amendment. The attached page is captioned "Version with markings to show changes made".

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Faithfully Yours,

Sergey Matasov, M.D.



Application/Control Number: 09/509,377
 Enclosure / to Applicant's reply of Sept. 1, 2004

Page 26

Reply under 37 CFR 1.116 -
 EXPEDITED PROCEDURE -
 Technology Center 3739

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,377	08/28/2000	Sergey Matasov		9553

United States Patent and Trademark Office
 Commissioner for Patents
 Art Unit 3739
 Examiner Mr. Leubecker, John P.
 P.O. Box 1450, Alexandria VA 22313-1450
 United States of America

EXAMINER	
LEUBECKER, JOHN P.	
ART UNIT	PAPER NUMBER

3739

DATE MAILED: September 3, 2003

VERSION WITH MARKINGS TO SHOW CHANGES MADE

RECEIVED
 CENTRAL FAX CENTER

SEP 02 2004

In the specification:

1. Paragraph, beginning at page 3, line 12 with has been amended as follows:

A compact hollow cylinder of the invaginator can be formed of tightly compressed in longitudinal and transverse directions pleats of different forms of an eversible thin-walled tube placed at any angles with the longitudinal axis of an endoscopic tube. The cylinder has recurrent narrowings of an external diameter and widenings of its internal diameter. The stability of diameters depends on the compactness of the cylinder. In one of the embodiments the definite compactness of cylinder ensures the gap with endoscopic tube during their joining and in the process of invagination, in the other - only during the joining. There are possible also the interim variants of embodiments.

In the claims:

Claims 1-20 have been amended by claims 1-20 as follows:

1. ~~An endoscope, comprising an invaginator of a thin-walled tube, which is compactly placed on the distal part of an endoscopic tube in the shape of small layers and/or pleats.~~
2. ~~The endoscope according to claim 1, wherein the said invaginator is formed in a hollow cylinder having a gap with the distal part of the endoscopic tube.~~
3. ~~The endoscope according to claim 2, wherein said gap is keeping under the working pressure in a cavity of invaginator.~~
4. ~~The endoscope according to any of claims 1 to 3, further comprising a distal coil of the endoscopic tube.~~
5. ~~The endoscope according to any of claims 1 to 3, further comprising a shell of invaginator for insertion in rectum.~~
6. ~~The endoscope according to any of claims 1 to 3, further comprising a preservative of the distal part of endoscopic tube.~~
7. ~~An endoscope, comprising a disposable cartridge for the invagination of endoscopic tube, which has:~~

Application/Control Number: 09/509,377
 Enclosure / to Applicant's reply of Sept. 1, 2004

Page 27

Reply under 37 CFR 1.116 -
 EXPEDITED PROCEDURE -
 Technology Center 3739

- an invaginator of a thin-walled tube, formed in the shape of small layers and/or pleats in a hollow cylinder having a gap with the distal part of endoscopic tube,
 - a distal seal of endoscopic tube,
 - a shell of invaginator for insertion in rectum,
 - a preservative of the distal part of endoscopic tube.
8. The endoscope according to claim 7, wherein said invaginator keeps said gap under the working pressure in the cavity of invaginator.
 9. The endoscope according to any of claims 1, 2, 3, 7, 8, further comprising a proximal seal of the endoscopic tube.
 10. The endoscope according to any of claims 1, 2, 3, 7, 8, further comprising a spring of invaginator.
 11. The endoscope according to any of claims 1, 2, 3, 7, 8, further comprising a tip of the endoscopic tube.
 12. The endoscope according to claim 11, wherein said tip comprises a protective glass.
 13. The endoscope according to claim 12, wherein said tip comprises a channel in the cavity of intestines.
 14. The endoscope according to any of claims 1, 2, 3, 7, 8, further comprising an anal dilator.
 15. The endoscope according to claim 14, wherein said anal dilator comprises a channel in the cavity of intestines.
 16. The endoscope according to any of claims 1, 2, 3, 7, 8, further comprising an endoscopic tube with a distal drive of traction lines, bending its distal end, made in the shape of cylinder/piston units.
 17. The endoscope according to any of claims 1, 2, 3, 7, 8, further comprising an endoscopic tube with a distal drive of traction lines, bending its distal end, made in the shape of cyphon.
 18. The endoscope according to any of claims 1, 2, 3, 7, 8, further comprising a biopsy forceps in the shape of a flexible hemotic tube, on the distal end of said tube a piston of biopsy channel is placed.
 19. The endoscope according to claim 18, further comprising a distal drive of cutters.
 20. An endoscope comprising a mechanism for insertion of endoscopic tube in the shape of cylinder/piston unit.

I claim:

1. An endoscope, comprising an invaginator, which is a thin-walled tube, compactly placed on the distal part of an endoscopic tube in the shape of small layers and/or pleats.
2. The endoscope according to claim 1, wherein said invaginator is formed in the shape of a compact hollow cylinder, which has a gap with the distal part of the endoscopic tube.
3. The endoscope according to claim 2, wherein said cylinder has a compactness, which ensures said gap in the process of invagination of the endoscopic tube.
4. The endoscope according to any of claims 1 to 3, further comprising a seal between the endoscopic tube and the unevorted end of said invaginator.
5. The endoscope according to any of claims 1 to 3, further comprising a shell of said invaginator, commensurate to the diameter of said invaginator and to the length of rectum.
6. The endoscope according to any of claims 1 to 3, further comprising a preservative of the distal part of the endoscopic tube.

Application/Control Number: 09/509,377
Enclosure / to Applicant's reply of Sept. 1, 2004

Page 28

Reply under 37 CFR 1.116 -
EXPEDITED PROCEDURE -
Technology Center 3739

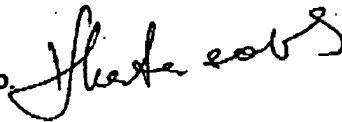
Application/Control Number: 09/509,377
Art Unit: 3739

Page 3

7. An endoscope, comprising a disposable cartridge for the invagination of an endoscopic tube, which has:
 - a invaginator which is a thin-walled tube, formed by small layers and/or pleats in the shape of a compact hollow cylinder, which has a gap with the distal part of the endoscopic tube,
 - a seal between the endoscopic tube and the unevverted end of said invaginator,
 - a shell of said invaginator, commensurate to the diameter of said invaginator and to the length of rectum,
 - a preservative of the distal part of the endoscopic tube,
8. The endoscope according to claim 7, wherein said cylinder has a compactness, which ensures said gap in the process of invagination of the endoscopic tube.
9. The endoscope according to any of claims 1, 2, 3, 7, 8, further comprising a seal of the endoscopic tube, which hermetizes a cavity of the everted part of said invaginator.
10. The endoscope according to any of claims 1, 2, 3, 7, 8, further comprising a spring of said invaginator.
11. The endoscope according to any of claims 1, 2, 3, 7, 8, further comprising a removable tip of the endoscopic tube.
12. The endoscope according to claim 11, wherein said tip further comprises a protective glass.
13. The endoscope according to claim 12, wherein a cavity of said tip communicates with a cavity of intestines.
14. The endoscope according to any of claims 1, 2, 3, 7, 8, further comprising an anal dilator.
15. The endoscope according to any of claims 1, 2, 3, 7, 8, wherein the endoscopic tube further comprises a distal drives of traction lines, bending its distal end, which are cylinder-piston units, connected to the pressure of gas or liquid.
16. The endoscope according to any of claims 1, 2, 3, 7, 8, further comprising a biopsy forceps, which are a flexible hermetic tube, on the distal end of said tube is placed a piston of a biopsy channel.
17. The endoscope according to claim 16, further comprising a distal drive of traction line of a cutters of said biopsy forceps.
18. An endoscope comprising a mechanism for introduction of an endoscopic tube, which is a cylinder-piston unit, connected to the pressure of gas or liquid.

Faithfully Yours,

Sergey Matasov, M.D.



Enclosure 9 to Applicant's reply of Sept. 1, 2004

Reply under 37 CFR 1.116 -
EXPEDITED PROCEDURE -
Technology Center 3739

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,377	08/28/2000	Sergey Matasov		9553

United States Patent and Trademark Office
Commissioner for Patents
Art Unit 3739
Examiner Mr. Leubecker, John P.
P.O. Box 1450, Alexandria VA 22313-1450
United States of America

EXAMINER	
LEUBECKER, JOHN P	
ART UNIT	PAPER NUMBER

3739

DATE MAILED: September 1, 2004

RECEIVED
CENTRAL FAX CENTER

SEP 02 2004

REMARKS / ARGUMENTS

Claims 1-20 have been amended.

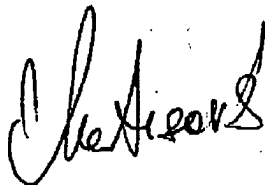
Examiner has acknowledged that claims 1-20 have now been amended to clear up all
Examiners' objections set forth in the last Office action.

Attached hereto is a marked-up version of the changes made to the specification, claims and
drawings by the current amendment. The attached page is captioned "Version with markings to
show changes made".

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Faithfully Yours,

Dr. Sergey Matasov



Application/Control Number: 09/509,377
 Enclosure 10 to Applicant's reply of Sept. 1, 2004

Page 1

Reply under 37 CFR 1.116 -
 EXPEDITED PROCEDURE -
 Technology Center 3739

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,377	08/28/2000	Sergey Matasov		9553

United States Patent and Trademark Office
 Commissioner for Patents
 Art Unit 3739
 Examiner Mr. Leubecker, John P.
 P.O. Box 1450, Alexandria VA 22313-1450
 United States of America

EXAMINER	
LEUBECKER, JOHN P.	
ART UNIT	PAPER NUMBER
	3739

DATE MAILED: September 1, 2004

VERSION WITH MARKINGS TO SHOW CHANGES MADE

RECEIVED
 CENTRAL FAX CENTER

SEP 02 2004

In the specification:

Endoscope
 with disposable cartridge for the invagination of endoscope tube

This is the continuation of application PCT/LV98/00006 based on the priority applications P-97-190 from 03.10.97 (LV) and P-98-188 from 23.09.98 (LV) and inventor's certificate № 1522466 from 21.08.78 (SU).

BACKGROUND OF THE INVENTION

1. Field of the Invention:

The invention ~~pertains~~ relates to the field of medicine, namely to colonoscopy and enteroscopy, but can also be used for industrial endoscopes.

2. Description of Background Art

The common feature of the known patents and of the solution proposed in this application is the presence of the everted tube, which transports endoscopic tube the endoscope, proposed in present application and of endoscopes according to known patents is a tube, eversible under fluid pressure. The inflated and everted tube invaginates an endoscope tube into explored channel and therefore was named by me as invaginator. For colonoscopy and enteroscopy one or another combination of invaginator with endoscopic tube must ensure the constantly opened objective of endoscopic tube. This purpose is pursued by the devices under the patents US 4,321,946 and US 4,615,334. The exploitation of invaginator is effective in case when it everts close to the objective and does not cover the latter.

The fluid pressure causes not only inflation and eversion of invaginator, but also its tight engagement with the endoscope tube. As a result of this engagement an everted part of invaginator becomes twice shorter than the endoscope tube.

Application/Control Number: 09/509,377
 Enclosure 10 to Applicant's reply of Sept. 1, 2004

Page 3

Reply under 37 CFR 1.118 -
 EXPEDITED PROCEDURE -
 Technology Center 3739

5,259,364 does not solve the problem of displacement of invaginator's uneverted part from chamber to objective.

Thus, all known endoscopes with invaginator are insufficiently effective or dangerous.

~~The named drawbacks exclude the possibility of clinical application of the known invaginators for the transportation of endoscopic tube.~~

~~The main drawback of widely applied manual colonoscopes difficulties of their introducing.~~

~~The second drawback is that bending of their distal end is possible only until a definite number of flexures of an endoscopic tube. The endoscope tube together with invaginator repeat all curves of explored channel. But bending of tube distal end is possible only till the definite number of curves. This is the second drawback of existing colonoscopes. Its Tube's end is bent by rotating of two rollers each connected to its pair of traction lines. Springs, comprising traction lines, on the distal end are continued by channels in the wall of cardan-jointed rings. Ends of traction lines are soldered to the distal ring of the cardan executive mechanism for bending the tube distal end. Outward extraction of traction line from the spring decreases gaps between cardan rings thus forming a small radius of a curve. Herewith At that the distal cardan ring pulls the opposite traction line in distal direction, thus ensuring an increase of space between rings. Difference of lengths of big and small half-circumferences of tube's curve is a product of « π » and diameter of an endoscope tube. Japanese authors point out that when 3-4 loops are formed, the distal end of an endoscope is was blocked, but biopsy forceps continued to function. This difference is explained by L. Aler formula~~

$$\frac{Q_1}{Q_2} = e^{\alpha f}$$

where: « Q_1 » - manual power realizing traction lines extraction; « Q_2 » - remaining from « Q_1 » power, attached to a distal cardan ring or cutters of biopsy forceps; « e » - basis of natural logarithm; « α » - traction line rotations in radians; « f » - friction index between a traction line and a spring. Under fixed values « Q_1 » and « f », value « Q_2 » depends on value « α », but for two consecutively connected traction lines of an endoscope the latter is twice as large as for one line of biopsy forceps.

The third drawback of known endoscopes is the problem of its maintenance. For recurrent use an endoscope tube is washed, disinfected and sterilized. However, there are reported cases of infecting patients with AIDS and other infections after endoscopy.

Application/Control Number: 09/509,377
Enclosure 10 to Applicant's reply of Sept. 1, 2004

Page 4

Reply under 37 CFR 1.116 -
EXPEDITED PROCEDURE -
Technology Center 3739

It has been practically proved that if an endoscope tube has more than 3-4 loops, it is impossible to introduce biopsy forceps into it and to take bioplate. This is the fourth drawback of the prototype.

SUMMARY OF THE INVENTION

The invention mainly pertains to the field of medicine and particularly is intended for the early diagnostics of colon cancer.

The objectives of the invention have been following: - ensure reliability, evenness and easiness of introduction of flexible endoscope tube into colon or others long flexuous channels due to the folded structure of invaginator and ensuring of invaginator's eversion directly under the objective; - ensure bending of the distal end of endoscope tube in flexuous channels; - make maintenance of an endoscope more convenient; - perform biopsy in flexuous channels. Implementation of these objectives will make colonoscopy available to any physician and make it easier for experienced endoscopists.

~~The objectives have been achieved by the fact that the claimed endoscope comprises:~~

- ~~■ an invaginator made of an everting tube, arranged by pleats, formed in the shape of compact hollow cylinder;~~
- ~~■ a disposable cartridge combining the invaginator with auxiliary elements;~~
- ~~■ an endoscopic tube ensuring fixation of a cartridge;~~
- ~~■ a mechanism for introduction of tube, ensuring together with a cartridge insertion of a tube;~~
- ~~■ a system of extraction traction of traction lines ensuring bending of the tube's distal end with hydro-manual or pneumo-manual or hydraulic or pneumatic drive;~~
- ~~■ a hydraulic or pneumatic intensifier of introduction and extraction of biopsy forceps and hydraulic or pneumatic intensifier of traction line of biopsy forceps.~~

As the base for all variants of the construction of present invention serves an endoscope with invaginator, whose uneverted end is coupled with the distal part of endoscope tube, at that the invaginator is made by pleats and in compact state is held on said distal part.

In the simplest variant of present invention, the uneverted part of invaginator is enclosed into the everted one, and the end of the everted part is fixed on a seal of endoscope tube and connected to fluid pressure.

In preferred embodiments of present invention the invaginator is made in the form of hollow compact flexible cylinder which has a gap with a preservative of the distal part of endoscope tube. A compact hollow cylinder of the invaginator is formed of tightly compressed in longitudinal

Application/Control Number: 09/509,377
Enclosure 10 to Applicant's reply of Sept. 1, 2004

Page 5

Reply under 37 CFR 1.116 -
EXPEDITED PROCEDURE -
Technology Center 3738

and transverse directions pleats of different forms of an eversible thin-walled elastic tube placed at any angles with the longitudinal axis of an endoscope tube. For its flexibility the cylinder could have recurrent narrowings of an external diameter and widenings of its internal diameter.

Preferred embodiments of present invention comprise a disposable sterile cartridge for the invagination of endoscope tube, the cartridge could comprise: - ~~A disposable sterile cartridge for invagination consists of~~ - a shell which has a projection at its proximal end, comprising wherein could be enclosed: a preservative of the distal part of endoscope tube which could be joined at the proximal end to a spring stop; a compressed spring; a spring distancer in which is located a distal seal of the endoscope tube coupled to an uneverted end of the invaginator; a fixator of compressed spring; an invaginator in the form of a hollow compact cylinder, which has a gap with preservative and could comprise a recurrent narrowings of an external diameter and widenings of its internal diameter, at that the everted end of invaginator is fastened on the distal end of said shell; - ~~while on the shell is located a proximal seal of the endoscopic tube with the - a proximal seal of the endoscope tube fastened on the distal end of said shell~~ but at the distal end of the shell the everted end of the invaginator is fastened; - an anal dilator having a channel in its wall; - a tip of said endoscope tube, coupled with the distal end of said preservative, which one (the tip) has a protective glass, a channel for glass washing and blowing of intestine, an element for hermetic joining to the endoscope tube.

In preferred embodiments of present invention the cartridge for invagination of endoscope tube could be attached to a mechanism for its introduction. The mechanism for introduction of the endoscopic tube ~~consists~~ could comprise a cylinder with two pistons, which are interconnected with distancers and segment of an elastic tube, but a cavity between them through a pedal cock communicates with fluid pressure, while a cavity between a proximal seal of the endoscope tube and a distal piston comprises a spring which returns pistons to their home position and through the pedal cock communicates with fluid pressure. The cylinder is joined with the cartridge for invagination of the endoscopic tube. The cavity between pistons and the elastic tube is connected to the source of pressure or atmosphere (negative pressure) through the cock. The cavity between the distal piston and the proximal seal of the endoscopic tube through the cock is connected to the source of negative pressure or atmosphere (overpressure).

~~An endoscopic tube is supplemented with:~~ In preferred embodiments of present invention the inserted endoscope tube could comprise for coupling with cartridge: - an internal transverse pleats of its external cover, which raise tube's flexibility; - two air-ducts, where the larger one has a lateral opening into a cavity of the proximal seal of the disposable cartridge for invagination, but the smaller one - into a cavity of distal and proximal preservatives; - an areas for hermetic fixation of ends of preservatives; - a proximal preservative. The cocks can be

Application/Control Number: 09/509,377
Enclosure 10 to Applicant's reply of Sept. 1, 2004

Page 6

Reply under 37 CFR 1.116 -
EXPEDITED PROCEDURE -
Technology Center 3739

placed in the pedals but the spring, which returns pistons to their home position can be located in the cavity between the proximal seal of endoscopic tube and the distal piston. At that a control block could be made as a desk unit, but the cock, which feeds the working pressure into the everted part of invaginator could be placed in pedal.

In preferred embodiments of present invention the system for bending of the distal end of endoscope tube in tortuous channels could comprise the ~~The system of extraction-intraction of traction lines ensuring management over the endoscopic tube's distal end, has a hydro-manual or pneumo-manual or hydraulic or pneumatic drive and creates exertion at the distal end of traction lines. The system includes sources of overpressure and negative fluid pressure, connected to cavities of elastic tubes. The elastic tubes could comprise springs with traction lines, the tubes could be fixed to springs by thread, but the springs could be executed with pitch. The traction lines on distal end could be joined with springs, but in the control block - with manual extractors-intractors of traction lines, connected with elements ensuring synchronous fluid evacuation from the cavity of manually extracted traction line and fluid feeding into the cavity of introduced traction line. On~~ The distal end of tube and traction line a cylinder can be placed whose piston is connected to a traction line. The unit cylinder/piston can be placed by sylphon. could be finished by cylinder and piston accordingly or the tube could be finished by an elastic element, for example by sylphone, but a traction line could be connected with sylphone's distal end correspondingly. A manual extractors-intractors of traction lines could be made in the manner of a rod, but the sources of overpressure and negative fluid pressure - in the manner of a piston and cylinder, positioned on the rod. An element ensuring synchronous feeding of negative pressure into fluid evacuation from the cavity of extracted traction line and fluid feeding overpressure into the cavity of introduced traction line could be made as a pinion mated with cogs of two rods. As Each of two pinions is coupled only with its pair of traction lines, that is why bending of the tube's end could be performed in two stages. The cross-piece with a management lever, wherein central part has a movable connection is movably connected with the body of the desk node of control block, but the ends are attached to four rods, pistons and cylinders, could ensures simultaneous bending of the tube's distal end in any direction.

In preferred embodiments of present invention in order to conduct biopsy in tortuous channels, the insertion and extraction of biopsy forceps could be realized with a help of fluid pressure ~~A hydraulic or pneumatic intensifier of introduction and extraction of biopsy forceps includes sources of overpressure and negative pressure, which are is connected through a cock to the cavity of the biopsy channel, the entrance to which is sealed by a seal of biopsy forceps, and at the distal end of which there is a piston of the biopsy channel. In addition At that the biopsy forceps comprise have an intensifier of traction lines and contain a flexible hermetic tube, which~~

Application/Control Number: 09/509,377
Enclosure 10 to Applicant's reply of Sept. 1, 2004

Page 7

Reply under 37 CFR 1.116 –
EXPEDITED PROCEDURE –
Technology Center 3739

is connected to source of fluid overpressure and negative pressure, but the distal end of the tube and traction lines could be finished ~~finishes~~ with a cylinder and a piston respectively. The unit cylinder-piston is possible to replace with a segment of syphon, the end of which is connected to traction line.

The subject of present invention is an endoscope, comprising

- an invaginator whose uneverted end is coupled with the distal part of the endoscope tube, at that said invaginator is held on said distal part of the endoscope tube;
- an invaginator formed of pleats, tightly compressed in longitudinal and transverse directions in a compact hollow cylinder, which has a gap with said distal part of the endoscope tube.

The subject of present invention also is an endoscope with a disposable cartridge for the invagination of endoscope tube, the cartridge comprises: invaginator whose uneverted end is coupled with the distal part of the endoscope tube, said invaginator is formed of pleats, tightly compressed in longitudinal and transverse directions in a compact hollow cylinder, which has a gap with said distal part of the endoscope tube and is held on said distal part.

Both foregoing subjects of invention could also comprise:

- said cylinder of invaginator having narrowings of external diameter and widenings of internal diameter,
- a shell for conducting the distal part of endoscope tube with invaginator along rectum, at that the diameter of said shell is commensurate to the diameter of said invaginator,
- sliding seals of endoscope tube, isolating a cavity of the everted part of invaginator,
- an anal dilator,
- said anal dilator with a channel in its wall,
- a spring of invaginator,
- a preservative of the distal part of endoscope tube united with tube's tip, at that the proximal end of preservative and the tip have areas for hermetic fixation to the distal part of said endoscope tube,
- said tip comprises a protective glass and communicates with intestinal cavity,
- a mechanism for introduction of the endoscope tube which is a cylinder-piston unit having a hermetic cavity, confined by a cylinder, a piston and a segment of an elastic tube connected to fluid pressure,
- an endoscope tube with distal drives of traction lines bending its distal end, which are springs executed with pitch and enclosed inside elastic tubes connected to fluid pressure,

Application/Control Number: 09/509,377
 Enclosure 10 to Applicant's reply of Sept. 1, 2004

Page 8

Reply under 37 CFR 1.116 -
 EXPEDITED PROCEDURE -
 Technology Center 3739

- o an endoscope tube with distal drives of traction lines bending its distal end, which are cylinder-piston units connected to fluid pressure.
- o an endoscope tube with distal drives of traction lines bending its distal end, which are sylphons connected to fluid pressure.
- o an endoscope tube with a biopsy channel connected to fluid pressure and a biopsy forceps which are flexible hermetic tube with a biopsy channel's piston on tube's distal end.
- o said biopsy forceps having a distal drive of forceps which is a cylinder-piston unit connected to fluid pressure.
- o said distal drive of forceps which is a sylphone connected to fluid pressure.

The subject of invention also is a method of prophylaxis from getting infected of endoscope tube and patient, the method comprises:

- o hermetic connection of endoscope tube to tube's distal part preservative an to a tip united with said preservative, having a protective glass and communication with intestinal cavity.
- o hermetic connection of said preservative to the uneverted end of invaginator of endoscope tube, which is an elastic tube everted under fluid pressure; the elastic tube is formed by pleats in a compact hollow cylinder which has a gap with said preservative.
- o feeding of fluid pressure through a channel in endoscope tube under the protective glass of said tip.

BRIEF DESCRIPTION OF THE DRAWINGS

The graphic materials explain the essence of invention, where FIG.1 represents a variant of endoscope with disposable cartridge for invagination, where: a - handle-shaped control block; b - distal part of endoscope tube with mounted cartridge; c - longitudinal section of cartridge; d, e, f - enlarged fragments of FIG.1c. On FIG.2 is shown the system of extraction-intracation of traction lines with a fluid-manual drive bending the distal end of endoscopic tube, in case when the distal end of endoscope is in direct position, where: a - position of system elements comprised in control block; b - enlarged fragment of FIG.2a; c - distal part of tube with "bared" system elements (vertical arrows show the top-bottom of endoscope tube); d - enlarged fragment of FIG.2c. On FIG.3 is represented the system of extraction-intracation of traction lines when the end of an endoscope endoscopic tube is bent downwards, where: a - position of elements contained in control block; b - enlarged fragment of FIG.3a; c - distal part of endoscope tube with "bared" elements (horizontal arrows show the direction of traction lines motion); d, e - enlarged fragments of FIG.3c. On FIG.4 are represented: a - control block and design of new endoscope; b - cross-piece with lever, rods, pistons and cylinders for bending

Application/Control Number: 09/509,377
Enclosure 10 to Applicant's reply of Sept. 1, 2004

Page 9

Reply under 37 CFR 1.116 –
EXPEDITED PROCEDURE –
Technology Center 3739

distal end of endoscope in any direction; c – construction of a mechanism for introduction of endoscope tube into cartridge; d - system of interaction introducing and extraction of biopsy forceps; e – intensifier of introduction and extraction of biopsy forceps. On FIG.5 is represented the simplest variant of present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The list of numerical markings of FIG.1-[4] 5 is given at the end of the specification.

A simplest variants of present invention could comprise (see FIG. 5): - a source 5 of excessive pressure; - an endoscope tube 3 with a control bloc 2 having a communication branch, a stop 11 for spring 10; - an invaginator of endoscope tube 3 which consists of everted part 4 and uneverted part enclosed in said part 4, at that the uneverted part of invaginator tightly adjoins to an endoscope tube and is placed by pleats perpendicularly to it. From the side of an uneverted end 7 the invaginator is supported by spring 10, but the place of transition of uneverted part of invaginator into its everted part 4 is limited by tip 6. Besides, the endoscope-prototype comprises: - an external (proximal) seal 13 of tube 3 on which the end 12 of the everted part 4 of invaginator is fixed by a ring 16; - rings 8, 9 on the uneverted end 7 of invaginator; - an air-duct 15 with a cock 17 for feeding of working pressure into a cavity 14 of the everted part 4 of invaginator; - an anal dilator 19.

The invaginator is to be everted under tip 6, but during the process of invagination the distal part of tube 3 becomes bared. It could happen both due to absence of gap between tube 3 and uneverted part of invaginator and to a friable structure of said uneverted part, which under the action of air pressure engages to tube 3.

The problem of engagement of the uneverted part of invaginator with the endoscope tube 3 was solved by invaginator formed of pleats tightly compressed in longitudinal and transverse directions in a compact hollow cylinder 23 (see FIG. 2), the cylinder has a gap 25 with the distal part of an endoscope tube 3 and for its flexibility could have a recurrent narrowings of external diameter and widenings of its internal diameter respectively.

A new endoscope comprises. Further follows more complicated variants of present invention (see FIG. 2, FIG. 3, FIG. 4) comprising an endoscope tube 3 with control block 2 and communication branch. There are possible, for example, a following constructions. Air-duct 15 and cock 17 positioned on control block 2 or in pedal, connect source of fluid working pressure with opening 21 into the cavity of seal 13, which communicates with cavity 14 of shell 22. The distal part of shell 22 is commensurable in relation to length and diameter to uneverted part of invaginator 23, but the proximal part – to the compressed spring 10. Everted end 12 of

Application/Control Number: 09/509,377
Enclosure 10 to Applicant's reply of Sept. 1, 2004

Page 10

Reply under 37 CFR 1.116 -
EXPEDITED PROCEDURE -
Technology Center 3739

invaginator 23 is connected to shell 22 by ring 16. Invaginator 23 has narrowings and widenings 24, as well as gap 25 with distal preservative 26, at that the gap 25 is keeping also at working pressure in the cavity 14. Ends of distal 26 and proximal 27 preservatives and corresponding to them places of tube 3 have areas 28 for interconnection and hermetization. Seal 29 on end 7 of invaginator 23 separates cavity 14 from cavity 25, which communicates with the intestinal cavity. A distancer 30 prevents deformation of seal 29 by spring 10. Ends of compressed spring 10 are based on distancer 30 and stop 11 at the end 28 of preservative 26. Stop 11, in its turn, is positioned on the projection 31 of shell 22. The distal end of preservative 26 ends with tip 6 with channels 32 for washing of protective glass 33 and blowing-up of intestines, as well as an element for connection to endoscope tube 3. On the border of narrow and broad parts of shell 22 there is an area of intermediate diameter with indented elastic ring 34 for fixation of compressed spring 10. Channel 35 of anal dilator 19 is used for decompression of intestines during intubation. In the tube 3, besides the enumerated, there are elastic tubes 36, 37 comprising springs 38, 39 and traction lines 40, 41. Tubes 36, 37 are connected to springs 38, 39 with thread 42. Near mechanism 43 for bending the distal end of tube 3, ends of tubes 36, 37 are closed with plugs 44, which also connect springs 38, 39 with traction lines 40, 41. Proximal ends of tubes 36, 37 are connected with sources 45 of overpressure and negative fluid pressure. Proximal ends of traction lines 40, 41 are connected with their manual extractors-intractors 46, but the latter - with element 47 which ensures synchronous feeding of negative pressure into evacuation of fluid from the cavity of which is being the extracted traction line 40 and of overpressure feeding of fluid into the cavity of which is being the introduced traction line 41.

Endoscope tube 3 has an internal pleats 48 of its external cover, air-duct 49 with two openings 50 designed for vacuum fixation of preservatives 26, 27 to tube 3 and also has a removable sleeve gasket 51. Control block 2 has a cock 52 of an air-duct 49. Seal 13 is hermetically connected to a mechanism 53 for introduction of endoscope tube 3. A mechanism 53 for introduction of tube 3 is operated by pedal 54, but lever 55 realizes bending of tubes end. Cylinder 56, two pistons 57, distancers 58 and segment of an elastic tube 59 confine a cavity 60, which is connected with source of overpressure fluid pressure by means of cock in pedal 54. Cavity 61 comprises return spring 62 and is connected with negative-pressure source of fluid pressure by means of cock in pedal 54. Seal 64 and nut 65 are mounted on biopsy forceps 63, but piston 66 is positioned at their distal end. Seat for seal 64 and nut 65 is located at entry 67 to biopsy channel, which is positioned with cock 68 on control block 2. Syphon 69, which serves as a source of overpressure and negative fluid pressure in the intensifier of traction line of biopsy forceps 63, could be combined with its handle.

Application/Control Number: 09/509,377
Enclosure 10 to Applicant's reply of Sept. 1, 2004

Page 11

Reply under 37 CFR 1.116 -
EXPEDITED PROCEDURE -
Technology Center 3739

Marks made on preservative 27 and tube 3 serves for their correct positioning. Then mechanism 53 is mounted on tube 3 and cartridge for invagination is fixed. Pressing of cock 52 will ensure vacuum fixation of preservatives 26, 27 to tube 3. After introduction of seal 13 into cylinder 56 endoscope preparation for work is completed.

After the patient has been placed on an endoscope table, a cartridge is oiled and introduced into the rectum and its ampoule is examined as if with a rigid rectoscope. The fluid pressure in cavity 14 is raised fed by pressing the cock 17 thus releasing the distancer 30 from coupling with fixator 34 and shell 22. Thereby spring 10 is released and it is possible to proceed with invagination of tube 3. Eversion of invaginator 23 and introduction of tube 3 into the colon occurs under fluid working pressure in cavity 14 at the moments of pressing pedal 54. During the endoscopy procedure intestines are to be distended. Gas into intestines is constantly supplied through gas/liquid channel of tube 3 and through channel 32 of tip 6 thus preventing getting penetrating of intestinal content under a protective glass 33. Gas evacuation from intestines occurs through a channel 35 of anal dilator 19.

Bending of mechanism 43 is realized by means of ~~overpressure and negative fluid~~ pressure sources 45, manual extractors-intractors 46 of traction lines 40, 41 and by means of elements 47 which ensure ~~feeding of negative pressure in the cavity of~~ evacuation of fluid from the tube 36 which comprises extracted traction line 40, and feeding of ~~overpressure~~ fluid in the cavity of tube 37 containing introduced traction line 41. ~~Due to negative pressure~~ As a result of fluid evacuation the elastic tube 36 and spring 38 are shortened. Considering, that their distal end is connected with traction line 40, this shortening relieves its manual extraction. ~~Due to Fluid~~ pressure in tube 37 the latter and spring 39 elongates towards executive mechanism 43 thus relieving manual intraction of traction line 41. Thread 42 twisted on tubes 36, 37, connects them with springs 38, 39. Thus, ~~negative pressure and overpressure which shorten and elongate tubes 36, 37 and springs 38, 39~~ evacuation and feeding of fluid ensure application of powers to distal ends of traction lines 40 and 41; manual extraction and intraction of traction lines 40, 41 creates synchronous efforts on their proximal ends. Mechanism 43 of tube 3 is bent downwards by the above-mentioned method. During bending of mechanism 43 upwards, all above enumerated elements are moved in opposite directions, but bending of mechanism 43 to the left and to the right is implemented by the second pair of traction lines, which work similarly. In intermediate positions mechanism 43 is bent by interchangeable application of both pairs of traction lines. Element 47 made in the shape of a crosspiece with lever 55 ensures simultaneous bending of mechanism 43 in any direction.

Application/Control Number: 09/509,377
Enclosure 10 to Applicant's reply of Sept. 1, 2004

Page 12

Reply under 37 CFR 1.116 --
EXPEDITED PROCEDURE --
Technology Center 3739

As during colonoscopy tube 3 repeats all natural flexures of the colon its extubation must not be accelerated. Anal dilator 19 through which extubation is to be conducted eliminates unpleasant sensations caused by this process.

The most practically important version of the invention is a colonoscope with endoscope tube 3 without biopsy channel. A disposable cartridge ensures an available to all and atraumatic transportation of tube 3 in the colon, preservatives 26, 27 protect the patient from infections seated in endoscope tube 3, but tube 3 - from getting contagious during endoscopy. The management ergonomics of such colonoscope also makes it available to any physician: during endoscopy a physician in sedentary position, watches the screen, presses pedal cock 17 with one foot, pedal 54 with another, the right hand controls lever 55, but in case of necessity washes the protective glass 33 by pressing on the cock with the left hand. Such colonoscope is necessary firstly for family doctors, gastroenterologists and surgeons for regular screening of colon cancer. Having selected "suspicious" patients out-patient physicians will direct them to an in-patient clinic for conducting biopsy and other thorough examination.

For realization of biopsy a cartridge with tip 6, without glass 33 is used. Having exhausted the possibility of manual insertion of forceps 63, it is necessary by means of seal 64 and nut 65 to hermetize entry 67 into the biopsy channel and connect it by means of cock 68 to the source of fluid pressure. Further insertion of forceps 63 is performed by their manual intraction and due to fluid pressure of liquid or gas on piston 66, but extraction - by switching cock 68 in the position «vacuum» and manual extraction of forceps 63. Due to location of source 69 of overpressure and negative fluid pressure of traction line intensifier in the handle of forceps, taking of bioplate is made as previously - approach of rings ensures movement of the traction line inwards, but detachment - extraction of the traction line.

Specifications of graphic materials' marks on FIG.1-4,5:

2 - control block with communication branch;

3 - endoscope tube;

4 - everted part of invaginator (on FIG. 5 only);

5 - source of working pressure in cavity 14 (on FIG. 5 only);

6 - tip of endoscope tube 3;

7 - uneverted end of invaginator 23;

8,9 - rings at the end 7 of invaginator (on FIG. 5 only);

10 - compressed spring;

11 - stop for spring 10;

12 - everted end of invaginator 23;

13 - proximal seal of tube 3;

Application/Control Number: 09/509,377
Enclosure 10 to Applicant's reply of Sept. 1, 2004

Page 13

Reply under 37 CFR 1.116 -
EXPEDITED PROCEDURE -
Technology Center 3739

-
- 14 - cavity of everted part 4 of invaginator 23;
 - 15 - air-duct for feeding fluid working pressure into cavity 14;
 - 16 - ring, fixing end 12 of invaginator 23;
 - 17 - cock of air-duct 15;
 - 18 - manometer (on FIG. 5 only);
 - 19 - anal dilator;
 - 20 - rectum (on FIG. 5 only);
 - 21 - air-duct 15 opening on tube 3;
 - 22 - shell of cartridge for invagination;
 - 23 - invaginator formed in a compact flexible cylinder;
 - 24 - narrowings and widenings of cylinder of invaginator 23;
 - 25 - gap (cavity) between cylinder of invaginator 23 and preservative 26;
 - 26 - distal preservative of tube 3;
 - 27 - proximal preservative of tube 3;
 - 28 - areas on tube 3 and at the ends of preservatives 26, 27 for their hermetic connection;
 - 29 - distal seal between tube 3 and end 7 of invaginator 23;
 - 30 - distancer between spring 10 and invaginator 23 comprising seal 29;
 - 31 - projection on shell 22 for stop 11;
 - 32 - channel in tip 6;
 - 33 - protective glass of tip 6;
 - 34 - elastic ring, fixing spring 10 in compressed state;
 - 35 - channel in anal dilator 19;
 - 36 - lower elastic tube of extractor-intractor of traction lines;
 - 37 - upper elastic tube of extractor-intractor of traction lines;
 - 38 - lower spring of extractor-intractor of traction lines;
 - 39 - upper spring of extractor-intractor of traction lines;
 - 40 - lower traction line of extractor-intractor of traction lines;
 - 41 - upper traction line of extractor-intractor of traction lines;
 - 42 - thread fixing elastic tubes 36, 37 to springs 38, 39;
 - 43 - mechanism for bending of distal end of tube 3;
 - 44 - plug closing tubes 36, 37 and connecting springs 38, 39 with traction lines 40, 41;
 - 45 - sources of ~~overpressure and negative fluid~~ pressure;
 - 46 - manual extractors-intractors of traction lines 40, 41;
 - 47 - element for extraction-intraction of one or two pairs of traction lines;
 - 48 - pleats of external cover of tube 3;
 - 49 - air-duct into cavity of preservatives 26, 27;
 - 50 - distal and proximal openings of air-duct 49 on tube 3;

Application/Control Number: 09/509,377
Enclosure 10 to Applicant's reply of Sept. 1, 2004

Page 14

Reply under 37 CFR 1.116 –
EXPEDITED PROCEDURE –
Technology Center 3739

-
- 51 - sleeve gasket;
 - 52 - air-duct 49 cock on control block 2;
 - 53 - mechanism for insertion of endoscope tube 3;
 - 54 - pedal for switching on mechanism 53;
 - 55 - lever of element 47, made in a shape of cross-piece;
 - 56 - cylinder of mechanism 53;
 - 57- pistons of cylinder 56;
 - 58 - distancers between pistons 57;
 - 59 - segment of elastic tube, attached to pistons 57;
 - 60 - hermetic cavity, enclosed by segment of elastic tube 59 and pistons 57;
 - 61 - hermetic cavity, enclosed by seal 13 and distal piston 57;
 - 62 - spring returning pistons 57 to home position;
 - 63 - biopsy forceps;
 - 64 - seal of entry 67 into biopsy channel;
 - 65 - nut, fixing seal 64;
 - 66 - piston of biopsy forceps;
 - 67 - entry into biopsy channel;
 - 68 - cock feeding the ~~overpressure or negative~~ fluid pressure into biopsy channel;
 - 69 - source of ~~overpressure and negative~~ fluid pressure connected with cavity of biopsy forceps 63;
 - 70 - cutters of biopsy forceps 63;
 - 71 - distal intensifier (drive) of traction line of the cutters 70.

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☒ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.